By:  Parker, Kacal H.B. No. 2185

A BILL TO BE ENTITLED

AN ACT

relating to the promotion of off-label uses of certain drugs, biological products, and devices.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1.  Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 444 to read as follows:

CHAPTER 444. OFF-LABEL USE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES

Sec. 444.001.  DEFINITIONS. In this chapter:

(1)  "Health care provider" means a person other than a physician who is licensed, certified, or otherwise authorized by the laws of this state to dispense or prescribe a prescription drug in the ordinary course of business or practice of a profession.

(2)  "Off-label use" means the use of a drug, biological product, or device approved for use by the United States Food and Drug Administration in a manner other than the use for which it is approved by the United States Food and Drug Administration.

(3)  "Physician" means a person licensed to practice medicine in this state.

(4)  "Third-party payer" means an insurance company, health benefit plan sponsor, or entity other than the patient or healthcare provider that pays for medical services provided to a patient.

Sec. 444.002.  PROMOTION OF OFF-LABEL USE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES. (a) Notwithstanding other law, a pharmaceutical manufacturer or a representative of a pharmaceutical manufacturer may promote, in the manufacturer's advertising or marketing materials or directly to a physician, health care provider, or third-party payer a medically truthful and accurate off-label use of a drug, biological product, or device.

(b)  A physician or health care provider may communicate or otherwise promote to a patient an off-label use of a drug, biological product, or device consistent with the off-label use promoted for that drug, product, or device, as applicable, by a pharmaceutical manufacturer under Subsection (a).

Sec. 444.003.  DISCIPLINARY ACTION PROHIBITED FOR PROMOTION OF OFF-LABEL USE. (a) A pharmaceutical manufacturer or a representative of a pharmaceutical manufacturer may not be prosecuted or be subject to disciplinary action, including a revocation of or refusal to renew a license or certification, for promoting an off-label use of a drug, biological product, or device under Section 444.002.

(b)  The state regulatory authority of a physician or health care provider may not revoke or refuse to renew the license or certificate of or otherwise impose a disciplinary action against a physician or health care provider who communicates or otherwise promotes an off-label use of a drug, biological product, or device under Section 444.002.

Sec. 444.004.  HEALTH BENEFIT PLAN COVERAGE FOR OFF-LABEL USE NOT REQUIRED. This chapter does not require a health benefit plan to provide health benefit coverage for an off-label use of a drug, biological product, or device.

Sec. 444.005.  USE OF STATE MONEY FOR CERTAIN PURPOSES PROHIBITED. This state or a local governmental entity may not use public money to enforce or to cooperate with the federal government in enforcing 21 U.S.C. Sections 331 and 335 against a pharmaceutical manufacturer or a representative of a pharmaceutical manufacturer for promoting an off-label use under Section 444.002.

SECTION 2.  Section 444.003, Health and Safety Code, as added by this Act, applies to a prosecution or disciplinary action initiated or pending on or after the effective date of this Act.

SECTION 3.  This Act takes effect September 1, 2021.